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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,020	03/27/2003	Amarjit Singh	U 013943-5	9010

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EXAMINER	
PRYOR, ALTON NATHANIEL	
ART UNIT	PAPER NUMBER
1616	
MAIL DATE	DELIVERY MODE
01/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/089,020	SINGH ET AL.	
	Examiner	Art Unit	
	ALTON N. PRYOR	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,8-11,15,19 and 25-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,8-11,15,19 and 25-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/21/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 10/21/08 have been fully considered but they are not persuasive. See argument below. Previous rejections not addressed below have been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1,2,4,5,8-11,15,19,25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saslawski et al. (WO 99/33448; 7/8/99) in view of Gibson et al. (US 6426340; 7/30/02) based on US Provisional 60/018202; 5/23/96). Saslawski et al. teach a multilayer tablet that can be made up of only two layers, i.e. a first layer (immediate or fast release layer) and second layer (prolonged release layer containing a nonbiodegrable, inert porous polymeric matrix). See page 2 lines 19-30. Saslawski et al. teach that both layers can contain the same active ingredient (page 4 lines 14-16). Saslawski et al. teach a wide selection of actives for the tablet including the instant nimesulide (naproxen). See page 4 line 14 - page 5 line 10. Saslawski et al. teach that fast and prolonged release layers can comprise wetting agents, pH regulators, lactose, starch, polyvinylidone, polyoxyethylene sorbitan monostearate, docusate sodium, magnesium stearate and croscarmellose. In addition to the above specified ingredients the prolonged release layer can comprise hydroxypropyl methylcellulose and sodium

lauryl sulfate. See page 9 line 10 – page 12. Saslawski et al teach that the tablet can be polymer film coated (page 15 lines 3-6, page 19 lines 12-15). Saslawski et al. do not exemplify a tablet comprising specifically nimesulide as the active along with all of the ingredients listed above. However, Saslawski et al. do suggest such a combination of ingredients. Saslawski et al. also do not teach the tablet comprising colloidal silicone dioxide. However, Gibson et al. teach that colloidal silicone dioxide is a common excipient used in immediate and controlled released tablet formulations (USPN '340 column 4 lines 47-60). Therefore, it would have been obvious to one having ordinary skill in the art to modify the invention of Saslawski et al. to include the silicone dioxide. One would have been motivated to do this since the silicone dioxide is a common excipient employed in immediate and control release formulations.

Response to Applicants Argument

Applicants argue that Nimesulide is not disclosed in WO '448. Nimesulide is distinct from Naproxen recited in the office action. Naproxen is not a NSAID compound like Nimesulide. The Examiner agrees with the Applicants' statement. However, it is important to note that WO '448 allows for the inclusion of NSAID compounds which would suggest the inclusion of Nimesulide (or the Sulfonanilide compound class). Although WO '448 does not specifically disclose Nimesulide or other sulfonanilides , WO '448 provides examples of NSAID compounds. Specifically note, WO '448 provides examples of NSAIDs such as or for example arylpropionic derivatives (page 5 lines 6-21). The use of the language such as/for example allows for the inclusion of NSAID compounds like Nimesulide which are not specifically recited in WO '448.

Applicants also argue that Nimesulide is a NSAID compound falling within the Sulfonanilide class. Although WO '448 discloses NSAID compounds, the reference does not recite the use of the sulfonanilide class of compounds like Nimesulide. WO '448 does not suggest the use of Nimesulide. The Examiner argues that WO '448 allows for the inclusion of NSAID compounds which would suggest the inclusion of Nimesulide (or the Sulfonanilide compound class). Although WO '448 does not specifically disclose Nimesulide or other sulfonanilides , WO '448 provides examples of NSAID compounds. Specifically note, WO '448 provides examples of NSAIDs such as or for example arylpropionic derivatives (page 5 lines 6-21). The use of the language such as/for example allows for the inclusion of NSAID compounds like Nimesulide which are not specifically recited in WO '448.

Applicants use WO 91/17774, WO 99/41233, Nalluri et al and Piel et al to point out that Nimesulide is practically insoluble in water and difficult to formulate. On the other hand, instant invention provides a formulation for poorly water soluble nimesulide with release controlling materials. The Examiner argues that WO '448 at page 4 lines 17-38 to page 8 line 29 employ a wide range of active substances having a wide range of solubility properties – some soluble some insoluble, some showing pH-dependent solubility and some not showing pH-dependent solubility. The references referred to by the Applicants disclose that Nimesulide is practically insoluble in water. WO '448 teaching that a wide range of actives in terms of solubility properties can be employed makes it obvious to include the poorly water soluble nimesulide.

WO '448 does not disclose or suggest a once-a-day controlled release composition as recited in the amended claims. WO '448 shows composition dissolution in a max of 9 hours in the Figures. WO '448 does not disclose the materials that would prolong the release of the active substance for a longer period of time. The Examiner argues that WO '448 suggests the same combination of ingredients with NSAID compounds as recited in instant claims (see 103(a) rejection above). Therefore, it obvious that WO '448 yields a formulation that has prolonged release of the active. WO '448 does not have to exemplify all scenarios of the disclosed formulation in order to render instant once a day/prolonged formulation obvious.

WO '448 and USPN 6426340 do not make claimed invention obvious. USPN '340 discloses silicon as a common excipient employed in immediate and controlled release tablet formulation. USPN '340 does not teach multilayered or bilayered tablet of nimesulide as claimed in instant invention. The Examiner argues that USPN '340 is used for the sole purpose of showing that silicon dioxide is a common excipient used in immediate and controlled release tablet formulations.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALTON N. PRYOR whose telephone number is (571)272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alton N. Pryor/
Primary Examiner, Art Unit 1616